



**Notification for New Use of a Food Contact Substance
Divergan HM**

Environmental Assessment

1. **Date:** March 7, 2003
2. **Name of Sponsor:** BASF Corporation
3. **Address:** N-MEN 3000 Continental Drive
Mount Olive, NJ 07828

4. Description of the Proposed Plan

a) Requested Action

BASF Corporation is seeking FDA approval for a new use of the food contact substance, Divergan HM.

Divergan HM is intended for single use. It is to be added to alcoholic beverages, including beer and wine, for the adsorption of heavy metal ions and sulfides. Divergan HM is completely removed from the beverages by filtration. The recommended use level is 80 g Divergan HM in 100 L.

b) Need for Action

Elevated metal content in alcoholic beverages must be reduced to meet acceptable levels. Divergan HM is intended to bind heavy metals and sulfides present in these products, and to substitute for Kalium Hexacyanoferrat (II), which also releases hydrogen cyanide, for this purpose. Divergan HM is reduced completely during filtration and, unlike Kalium Hexacyanoferrat (II), can be used in applications where the copper content exceeds the iron content. Divergan HM can be used at different stages during wine treatment. When added to wine, it can bind approximately 90% of copper and iron in the immature wine, and approximately 75% of copper and iron in mature wine.

c) Locations of Use

Divergan HM will be used at alcoholic beverage production facilities at various locations around the country.

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d) Locations of Disposal

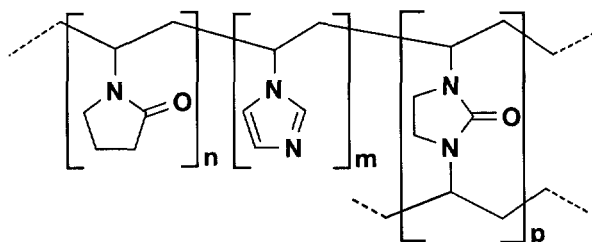
BASF Corporation expects that Divergan HM will be disposed of along with municipal solid waste, i.e., deposited in municipal solid waste landfills or combusted along with municipal solid waste.

5. Identification of Substances that are the Subject of the Proposed Action

Divergan HM is a cross-linked, insoluble, powdery and slightly hygroscopic terpolymer of N-vinylimidazole (CAS No. 1072-63-5, 90%), N-vinyl-2-pyrrolidinone (CAS No. 88-12-0, 7%), and N, N'-divinyl-imidazolidin-2-one (CAS No. 13811-50-2, 3%). The low molecular weight fraction (THF soluble) is < 1%. The maximal residual monomer content is < 5 ppm for the respective monomers

Molecular Formula: $(C_6H_9NO)_n(C_5H_6N_2)_m(C_7H_{10}N_2O)_p$

Structural Formula:



The Safety Data Sheet for Divergan HM is attached.

6. Introduction of Substances into the Environment

a) Introduction of Substances into the Environment as a Result of Manufacture

No extraordinary circumstances apply to the manufacture of the food-contact substance.

b) Introduction of Substances into the Environment as a Result of Use

Little or no introduction of Divergan HM into the environment will result from its use. Divergan HM is insoluble in alcoholic beverages, and will be completely removed from the beverages by filtration.

c) Introduction of Substances into the Environment as a Result of Disposal

Divergan HM is intended for single use, after which it will be disposed of in municipal solid waste landfills and/or incinerators.

BASF expects insignificant levels of the substance to migrate in landfills because: (1) migration studies submitted to FDA (as Attachment 8 to the January 7, 2003 submission) demonstrate insignificant migration potential; (2) the intended levels of use of Divergan HM are small (80 g Divergan HM per 100 L); and (3) Divergan HM is highly insoluble. Furthermore, the introduction of Divergan HM into the environment will not threaten a violation of the Environment Protection Agency's regulation in 40 C.F.R. Part 258 that pertain to landfills.

Divergan HM is composed of carbon, hydrogen, and nitrogen, elements commonly found in municipal solid waste. The complete combustion of this substance will produce carbon dioxide, water, and oxides of nitrogen. Because the market volume^{1/} of the food-contact substance is a very small fraction of the municipal solid waste generated and disposed in the United States, adding this substance to waste that is combusted will not significantly alter the emissions from municipal waste combustors. Because of the low levels of the combustion products compared to the amounts currently generated by municipal waste combustors, BASF Corporation does not expect that the combustion of Divergan HM will cause municipal waste combustors to threaten a violation of applicable federal and state emissions laws and regulations.

7. Fate of Substances Released into the Environment

No information need be provided on the fate of substances released into the environment, because, as discussed under Item 6 above, only minute quantities, if any, of substances will be introduced into the environment as a results of the use and/or disposal of Divergan HM. Therefore, the use and disposal of Divergan HM is not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

8. Environmental Effects of Released Substances

No information need be provided, because, as discussed under Item 6 above, only minute quantities, if any, of substances will be introduced into the environment as a result of the use and/or disposal of Divergan HM. Therefore, the use and disposal of Divergan HM is not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources

^{1/} Pursuant to 21 C.F.R. § 25.40(d), BASF Corporation incorporates by reference the market volume calculation present in the environmental assessment for FCN 141 for the same food contact substance.

Divergan HM is intended to bind heavy metals and sulfides present in alcoholic beverages, and to substitute for Kalium Hexacyanoferrat (II), which is less protective of the environment. Thus, there is no anticipated effect on the use of natural resources and energy associated with the proposed substitute.

10. Mitigation Measures:

Mitigation measures to the proposed action need not be considered because no potential adverse effects have been identified.

11. Alternatives to the Proposed Action

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

12. List of Preparers

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13. Certification

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of BASF Corporation."

(Date)

7 March 2003

(Signature of Preparer)

Suzanne A. Matuszewski Manager Regulatory Affairs &
(Name and Title of Preparer, Printed) Product Stewardship

14. References

The cross-linked terpolymer of N-vinylimidazole, N-vinyl-2-pyrrolidinone, and N, N'-divinyl-imidazolidin-2-one, was the subject of Food Contact Notification 141 (Gordon Burns and Robert Ellsworth) for the intended use "as a component of matrix filter sheets, for removal of metals and sulfides in alcoholic beverages using repeat-usage filtering equipment." FDA issued a finding of no significant impact in response to the environmental assessment. Pursuant to 21 C.F.R. 25.40(d), BASF Corporation, incorporates by reference, the environmental assessment from Food Contact Notification 141.

15. Attachments

Divergan HM Safety Data Sheet